

REMARKS

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

Claim Rejections Under 35 USC 112, Second Paragraph

Applicants submit the claims are fully supported by Example 6. Example 6 shows that an antibody having neutralizing activity to tissue factor suppresses the growth of the blood vessel tissue itself caused by expression of the tissue factor. See page 41, lines 10 to 11, which explicitly recites “suppressing the growth of the blood vessel tissues.” Therefore, the language of claim 45 is explicitly supported by the specification and does not constitute new matter. Moreover, amended claim 45 recites that the blood vessels are those “caused by expression of tissue factor” and the antibody is one that has “neutralizing activity” to human tissue factor.

Claim Rejections Under 35 USC 112, First Paragraph

“The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosure in the patent coupled with information known in the art without undue experimentation” MPEP § 2164, quoting from *United States v. Telectronics, Inc.*, 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988). “The test of enablement is not whether experimentation is necessary, but whether, if experimentation is necessary, it is undue.” MPEP § 2164, quoting from *In re Angstadt*, 537 F.2d 498, 504, 190 USPQ 214, 219 (CCPA 1976). The fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation. *In re Certain Limited-Charge Cell Culture Microcarriers*, 221 USPQ 1165, 1174 (Int'l Trade Comm'n 1983), *aff'd. sub nom., Massachusetts Institute of Technology v. A.B. Fortia*, 774 F.2d 1104, 227 USPQ 428 (Fed. Cir. 1985). Applicants contend, that under the guidelines of *In re Wands*, 8583 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988), it would not require undue experimentation to carry out the present invention.

As in *Wands*, a high level of skill existed at the time of filing and the methods needed to practice the invention (assays and animal models for measuring angiogenesis and

neovascularization) were well known at the time of filing. Moreover, as noted in the attached Exhibit A, Zhang et al. J. Clin. Invest. Vol. 94, 1994, p 1320-1327, before the priority date of the present application, it was known that the growth of blood vessel tissues causes not only restenosis but also angiogenesis and neovascularization. See for example, the second paragraph at page 1320, which states “tissue factor controls the balance of anogenic and antiangiogenic tumor cell activities.” The last sentence of the first full paragraph on page 1326 states “These studies emphasize the integral role that tissue factor has in tumor biology, in addition to the well known function as the central procoagulant cofactor which initiates activation of the coagulation pathway.” Therefore, given that animal models for measuring angiogenesis and neovascularization were available and that it was known that the growth of blood vessel tissues causes angiogenesis and neovascularization, one of skill in art could have practiced the present invention without undue experimentation. Accordingly, the present rejections should be withdrawn.

Conclusion

Applicants believe that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested. The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,



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